UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,780	12/03/2004	Bernard Allan	016325-013600US	2827

20350 7590 07/05/2007
TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
SAOUD, CHRISTINE J	
ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
07/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/516,780	ALLAN ET AL.	
	Examiner	Art Unit	
	Christine Saoud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-28* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I-X, claim(s) 1-3 and 6-7, drawn to method of identifying an agent for treating a diabetic or pre-diabetic individual by contacting an agent with a polypeptide encoded by one of SEQ ID NO:2, 6, 8, 10, 16, 20, 22, 28, 30 or 34, and selecting an agent that modulates the expression of the polypeptide.

Group XI-XX, claim(s) 1-2, 4 and 6-7, drawn to method of identifying an agent for treating a diabetic or pre-diabetic individual by contacting an agent with a polypeptide encoded by one of SEQ ID NO:2, 6, 8, 10, 16, 20, 22, 28, 30 or 34, and selecting an agent that modulates the activity of the polypeptide.

Group XXI-XXX, claim(s) 1-2 and 5-7, drawn to method of identifying an agent for treating a diabetic or pre-diabetic individual by contacting an agent with a polypeptide encoded by one of SEQ ID NO:2, 6, 8, 10, 16, 20, 22, 28, 30 or 34, and selecting an agent that binds to the polypeptide.

Group XXXI-XL, claim(s) 8-11, drawn to method of treating a diabetic or pre-diabetic animal comprising administering an antibody that binds one of SEQ ID NO:2, 6, 8, 10, 16, 20, 22, 28, 30 or 34.

Group XLI-L, claim(s) 12-18, drawn to method of introducing into a cell an expression cassette comprising a promoter linked to a polynucleotide encoding a polypeptide wherein the polynucleotide hybridizes to a nucleic acid encoding or wherein the polypeptide comprise one of SEQ ID NO:2, 6, 8, 10, 16, 20, 22, 28, 30 or 34.

Group LI-LX, claim(s) 19-21 and 24, drawn to method of diagnosing diabetes or pre-diabetes comprising detecting the level of a polypeptide encoded by a nucleic acid which hybridizes to one of SEQ ID NO:2, 6, 8, 10, 16, 20, 22, 28, 30 or 34.

Group LXI-LXX, claim(s) 19 and 21-24, drawn to method of diagnosing diabetes or pre-diabetes comprising detecting the level of a polynucleotide which hybridizes to a nucleic acid encoding one of SEQ ID NO:2, 6, 8, 10, 16, 20, 22, 28, 30 or 34.

Group LXXI, claim(s) 25-28, drawn to a nucleic acid encoding a polypeptide comprising SE ID NO:10, an expression cassette comprising the nucleic acid and a host cell comprising the expression cassette.

Group LXXII, claim(s) 25-28, drawn to a nucleic acid encoding a polypeptide comprising SE ID NO:28, an expression cassette comprising the nucleic acid and a host cell comprising the expression cassette.

The inventions listed as Groups I-LXIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The method of Group I is not a contribution over the prior art. According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as Groups I-XXX do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The technical feature of Group I is selecting an agent that modulates expression of a polypeptide encoded by a nucleic acid that hybridizes under stringent conditions to a nucleic acid encoding SEQ ID NO:2, which is shown by US 6,225120 to lack the novelty or inventive step of such selection as shown at column 4, lines 42-57 and column 5, lines 12-25 and column 51, line 59 through column 52, line 67, and does not make it a contribution over the prior art. Further, each of SEQ ID NO: 2, 6, 8, 10, 16, 20, 22, 28, 30 or 34 is structurally and functionally different (see pages 60-71 of the specification). Even SEQ ID NO:6 and 8, which are splice variants of each other are significantly structurally different and have not been shown to share a common function pertinent to the claimed inventions. It is noted that there are not limiting hybridization conditions defined in the specification or claims and, therefore, the agent which contacts the polypeptide encoded by the nucleic acid that hybridizes to a nucleic acid encoding SEQ ID NO:2 includes polypeptides described in and encoded by nucleic acids disclosed in US 6,225,120. The additional methods of Group XXXI-LXX are each separate methods that do not share a special technical feature of Group I or with each other because they require different components and method steps and have different objectives. Because the nucleic acids of Groups LXXI and LXXII are not the first product claimed, the method of using them are rightfully separated. This Authority therefore considers that the many inventions do not share a special technical feature within the meaning of PCT Rule 13.2 and thus do not relate to a single general inventive concept within the meaning of PCT Rule 13.1.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re*

Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 571-272-0891. The examiner can normally be reached on Monday-Friday, 6AM-2PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christine Saoud
Primary Examiner, AU 1646
June 22, 2007

CHRISTINE J. SAOUD
PRIMARY EXAMINER
Christine J. Saoud